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WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER

GETZOW, SCOTT M

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,248

Applicant(s)

DIORENZO, DANIEL JOHN

Examiner

Scott M. Getzow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-193 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-173 and 176-193 is/are rejected.
- 7) ☒ Claim(s) 174 and 175 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claim Objections

1. Claims 86-193 are objected to because of the following informalities: there are two claims 86. The claims after claim 86 must be renumbered. Appropriate correction is required.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the microelectrode and microelectrode shaft must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not set forth method steps.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8-14,27,32,33,36-41,45-48,54-89,94-106,108,121-135,139-148,150,151,154,157-159,170-172,177,184-186 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al (6016449).

Figure 2 shows all of the structure of claims 8 and 9. Figure 21 shows bone screws 623 as well as a flange 622 that helps stabilize the unit in the patient's skull. Figure 23 shows a sensor/actuator 850. Figure 19 shows a cap 636 with

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coils in it. Col. 6, lines 20+ teach that blood pressure can be sensed. Col. 12, line 45+ teaches electromagnetic and electronic power conversion. Col. 25, lines 45+ teach a catheter which delivers drugs to the CNS. Col. 26, lines 18+ teaches that both drug delivery and electrical stimulation can be used together. Col. 30, line 53 teaches that tremor can be detected and used. Col. 32 lines 8+ teach that intracranial electrodes can be used.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7,28,34,35,42-44,49-53,90-93,107,109-120,136-138,149,152,153,155,156,160-169,178-183,187-193 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.

The subject matter of the above claims is considered to be obvious over the teaching of Fischell, when viewed by the ordinarily skilled artisan. The various dimensions recited for the system, such as less than 10 inches, as in claim 50, is considered to be a design choice that the designer would make based on the size of the patient's skull. Re claims 90-93, the ordinarily skilled artisan would have known that to change the stimulation periodically would reduce habituation. Further, the use of a microelectrode is considered to be obvious in that to reduce

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the size of the electrode is considered to be desirable to be able to pinpoint the exact location of sensing and stimulation.

8. Claims 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al in view of Honig (3218638).

To use a multiplicity of orthogonal coils, as shown in Honig, would allow for the head of a patient to move in a variety of directions without loss of data/power since many directions for data/power transfer are covered.

9. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al in view of Schwartz et al (3522811).

To make the holder cloth, or to serve the function of a headrest or pillow, is considered to be obvious over the teachings of Schwartz in col. 5, lines 5-13 that teaches that the coils can be in a pillow.

10. Claims 173,176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al (6094598).

Figure 12 of Elsberry shows an intracranial catheter with two electrodes 38,40.

To make one of the electrodes a microelectrode would have been obvious and desirable since by doing such a more focused sensing/stimulation can be achieved, without damaging other tissues.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 85,94,121,128,150 are rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-6 of U.S.

Patent No. 6,366,813. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are considered to be obvious over the claims of the parent patent.

13. Claims 8,9,77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,366,813 in view of Fischell et al. To use a power conversion unit, as taught in Fischell, with the device described by claims 1-6 of the parent patent is considered to have been obvious

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in that such a power conversion system would allow for conveniently recharging the implanted device.


Allowable Subject Matter

14. Claims 174,175 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Scott M. Getzow
Primary Examiner

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